

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND
COMPOUNDING PHARMACY, INC.
PRODUCTS LIABILITY LITIGATION

v.

MDL No: 1:13-md-2419-FDS

This Document Relates to:

Montee v. BKC Pain Specialists LLC, et al.,
No: 1:13-cv-12657-FDS

**Motion for Leave to File in
Excess of Twenty (20) Pages
Allowed on 2/7/14**

Cooper v. BKC Pain Specialists, LLC, et al.
No: 1:13-cv-12658-FDS

Cooper v. BKC Pain Specialists, LLC, et al.
No: 1:13-cv-12659-FDS

**DEFENDANTS, BKC PAIN SPECIALISTS,
ADIL KATABAY, M.D. AND NIKESH BATRA, M.D.’S
CONSOLIDATED MEMORANDUM OF LAW IN SUPPORT OF
THEIR MOTION TO DISMISS**

I. INTRODUCTION

Defendants Nikesh Batra, M.D., Adil Katabay, M.D. and BKC Pain Specialists, LLC. submit this consolidated memorandum of law in support of their respective Motions to Dismiss as to Montee v. BKC Pain Specialists LLC. et al No: 1:13-cv-12657-FDS; Cooper v. BKC Pain Specialists, LLC et al No: 1:13-cv-12658-FDS; and Cooper v. BKC Pain Specialist LLC et al No. 1:13-cv-12659-FDS., respectively. The three actions arise out of the administration of a steroid—preservative free methylprednisolone acetate (“MPA”)--- manufactured and sold by New England Compounding Pharmacy Inc. (“NECC”). It is alleged that as a result of negligent manufacturing and sterilization practices certain vials or batches of MPA became contaminated with fungus that ultimately caused injury or harm to patients who received the MPA from their

healthcare providers or clinics that had purchased the medication from NECC. It is alleged that the tainted vials were included in certain lots and specifically Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013 which were recalled by NECC in September, 2012.¹ As more fully set forth below, defendants are entitled to dismissal of the Complaint for failure to state a claim upon which relief can be granted.

II. STATEMENT OF THE CASE AND RELEVANT FACTS

Three plaintiffs in these actions (Donna Montee, Brandi Cooper and Pamela Cooper) allege that they received MPA injections from BKC Pain Specialist, LLC and specifically from either Dr. Katabay or Dr. Batra, their treating physician at BKC. All three actions were initially filed in the Northern District of Ohio before being transferred to the MDL docket for In re: New England Compounding Pharmacy Inc, Products Liability Litigation. In addition to BKC Pain Specialist and Dr. Katabay or Dr. Batra, all three actions included as defendants various NECC related or affiliated individuals or entities.²

The claims against the NECC related or affiliated defendants center on negligent manufacturing and sterility practices including as to the maintenance of the “clean room” which led to the medication being exposed or contaminated by fungus. Desperate for more pockets, plaintiffs have opted to bring claims against any health care provider or clinic that purchased the medication from NECC and administered it to any patient. The gravamen of the claims is that

¹ The Lot Number denotes the date of the lot’s manufacture or compounding.

² These defendants include Ameridose LLC., GDC Properties Management, LLC, Medical Sales Management, Inc., Medical Sales Management SW, Inc., Barry Cadden, Gregory Conigliano, Lisa Cadden, Douglas Conigliaro, and Glenn Chin. An additional defendant includes ARL Bio Pharma Inc. It is alleged that Ameridose is a distribution center owned and controlled by NECC with it also alleged that NECC and Ameridose used MSM and MSMSW for marketing and sales functions. ARL, in turn, is alleged to have been retained by NECC to provide sterility testing, services and information to NECC. GDC was the owner or lessor of the premises leased by NECC where NECC operated. The individuals named (Conigliaros and Caddens) are alleged to be the owners, pharmacists and/or managers of NECC.

such clinics had a duty of “due diligence” before purchasing the MPA and that state regulations require individual prescription in the purchase of such compounding medications. Plaintiffs even allege as far as asserting an “agency” relationship with NECC and seeking to impose inapplicable product liability law on the healthcare providers. It is undisputed that the healthcare clinics and providers played no role in the manufacturing or sterility practices of NECC and had no knowledge of any contamination of the drug. None of the plaintiffs in these three actions ever developed any fungal infection or meningitis.

Following transfer to the MDL, all three plaintiffs (Cooper (2) and Montee) proceeded to adopt the Short Form Complaint. In the Short Form Complaint, through incorporation by reference to the Master Complaint, Montee, B. Cooper, and P. Cooper have set forth multiple (and identical) causes of action against Dr. Batra and/or Dr. Katabay and BKC Pain. They have asserted the following causes of action: 1) Negligence and Gross Negligence (Count III), 2) Violations of Consumer Protection Statutes, O.R.C. § 1345.01 *et seq.* and O.A.C. § 109:4-3-01 *et seq.* (Count IV), 3) Battery (Count VII), 4) Failure to Warn (Count VIII), 5) Ohio Products Liability Claims (Count IX), 6) Agency (Count X), 6) Civil Conspiracy (Count XI), and 7) Punitive Damages (Count XIV). *See* Short Form Complaints.

**a. Donna Montee (Montee v. BKC Pain Specialists LLC, et al.,
No: 1:13-cv-12657-FDS)**

Donna Montee alleges that on or about September 4, 2012, September 18, 2012 and October 2, 2012, Dr. Batra performed an epidural injection procedure on her. Donna Montee Short Form Complaint, Docket No. 27. It is alleged that the MPA used during the injection procedures was drawn from the vials that were part of three lots of contaminated MPA recalled by NECC. *Id.* Following the procedures, Ms. Montee claims to have begun experiencing flu-like symptoms, including head and body aches, fatigue, fever, confusion and dizziness. *Id.*

Nearly three weeks after her last injection, Ms. Montee was informed by BKC Pain about the preservative-free MPA recall instituted by NECC and that she may have received an injection from one or more of the contaminated lots. Montee Short Form Complaint. After learning such information, on or about October 15, 2012, Ms. Montee went to the emergency room to be evaluated. *Id.* The evaluation included the performance of a spinal tap, the results of which were abnormal. *Id.* Due to the abnormal results, Ms. Montee was hospitalized for several days for observation. *Id.* After her hospital stay, she was placed on medication and underwent several spinal taps and MRIs. *Id.* As a result of said tests, Ms. Montee claims to have experienced both physical and emotional pain and suffering. *Id.*

b. Brandy Cooper (B. Cooper v. BKC Pain Specialists et. al. 1:13-cv-12658-FDS)

On or about March 21, 2012, Dr. Katabay performed a cervical epidural injection procedure on Brandy Cooper which involved the injection of medication directly into her cervical spine. *See* Brandy L. Cooper and Leon D. Cooper Short Form Complaint, Docket No. 23 (hereinafter referred to as “B. Cooper Short Form Complaint”). Subsequently, on or about May 30, 2012 and June 18, 2012, Dr. Katabay performed similar epidural steroid injection procedures on Ms. Cooper. *Id.* According to Plaintiffs, the medication used in at least one of the procedures was preservative-free MPA compounded by NECC. *Id.* Significantly, none of the medication used in the three steroid injection procedures performed on Brandy Cooper came from any of the contaminated lots of preservative-free MPA produced by NECC and used by Dr. Katabay. *See* Affidavit of Adil Katabay, M.D.; attached hereto as Exhibit “A”.

Nearly four months after Brandy Cooper’s last injection procedure, on or about October 17, 2012, she claims to have developed pain and other symptoms, including nausea and a stiff neck. *Id.* Upon the development of such symptoms, she was advised to go to an emergency

room to be evaluated for fungal meningitis. *Id.* The evaluation consisted of numerous medical tests, including punctures and diagnostic imagining. *Id.* As a result of said tests, Brandy Cooper claims to have experienced both physical and emotional pain and suffering. *Id.* In addition, Plaintiff Leon D. Cooper, Brandy Cooper's husband, alleges to have sustained damages as a result of the loss of his wife's services due to her physical and emotional pain and suffering. *Id.*

c. Pamela Cooper (P. Cooper & D. Cooper v. BKC Pain Specialists, Inc, 1:13-cv-12659-FDS)

Pamela Cooper alleges that on September 24, 2012 and October 1, 2012, respectively, Dr. Katabay performed an epidural steroidal injection procedure on her. Pamela Cooper Short Form Complaint, Docket No. 23. The medication used in the procedure was preservative-free MPA compounded by NECC. *Id.* Approximately one month after the second injection, P. Cooper claims to have developed pain and other symptoms, including a stiff neck and headaches. *Id.* Following the development of such symptoms, Ms. Cooper was advised to go to the nearest emergency room to be evaluated for fungal meningitis, which included the performance of punctures and diagnostic imagining. *Id.* As a result of said tests, P. Cooper claims to have experienced both physical and emotional pain and suffering. *Id.* In addition to Ms. Cooper's claims, Plaintiff David L. Cooper, Ms. Cooper's husband, alleges to have sustained damages as a result of the loss of his wife's services due to her physical and emotional pain and suffering. *Id.*

III. STANDARD

To survive a motion to dismiss, plaintiff must allege facts that "raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)(quoting *Twombly*, 550 U.S. at 556). The Court need not accept the plaintiff's legal

conclusions as true or other “labels and conclusions” as “formulaic recitation of a cause of action’s elements will not do.” *Twombly*, 550 U.S. at 555. Similarly, the Court should not credit bald assertions or legal conclusions “couched as facts.” *Air Sunshine, Inc. v. Carl*, 663 F. 3d 27, 33 (1st Cir. 2011). Dismissal is appropriate if plaintiff’s well-pleaded facts do not “possess enough heft to show that plaintiff is entitled to relief.” *Ruiz Rivera v. Pfizer Pharms., LLC*, 521 F.3d 76, 84 (1st Cir. 2008) (quotations and original alterations omitted).

IV. LAW AND ARGUMENT

A. **Brandy Cooper Did Not Receive Any Injections from Any of the Contaminated Lots of Preservative-Free MPA Produced by NECC.**

As to the Brandy Cooper action it is undisputed that while Ms. Cooper received three MPA injections from Dr. Katabay as part of her treatment at BKC Pain Specialists, none of the compounded medication came from the lots that were determined to be contaminated and later recalled by NECC. *See* Affidavit of Adil Katabay, M.D. Accordingly,, none of the injections Dr. Katabay performed on Brandy Cooper contained contaminated preservative-free MPA.

As the sole basis for Brandy Cooper and Leon Cooper’s claims is that Brandy Cooper received injections from the contaminated lots of preservative-free MPA, the fact that she did not receive any injections from any contaminated lots is fatal to all of the claims Plaintiffs’ have set forth in their Complaint. Quite simply, Plaintiffs cannot establish Dr. Katabay and/or BKC Pain breached any duty or engaged in any wrongdoing with respect to Brandy Cooper. Accordingly, all of Brandy Cooper and Leon Cooper’s claims against Dr. Katabay and BKC Pain must be dismissed.

B. Plaintiffs' Complaints Fail to Sufficiently Allege Claims for Negligence and Gross Negligence.

1. Ohio law does not impose any of the "duties" alleged by Plaintiffs in their Complaints.

In Count III of their respective Complaints, plaintiffs sets forth what appears to be a laundry list of "duties" Dr. Batra and/or Dr. Katabay and BKC Pain allegedly owed to them as a result of the physician-patient relationship. Under the guise of these "duties", it is essentially alleged that Dr. Batra/Dr. Katabay and BKC Pain were required to investigate and supervise NECC's compounding procedures and production facilities and engage in a "due diligence" of sorts prior to lawfully purchasing preservative-free MPA from NECC. However, no such duties exist under Ohio law. Accordingly, Count III of Plaintiffs' respective Complaints fail to state a claim upon which relief can be granted.

Under Ohio law, a plaintiff must allege sufficient facts to meet each element of a negligence claim: "the existence of a duty, a breach of the duty, and an injury proximately resulting therefrom." *Middleton v. Rogers Ltd., Inc.*, 804 F. Supp. 2d 632, 639 (S.D. Ohio 2011), citing *Nageotte v. Cafaro Co.*, 160 Ohio App.3d 702, 828 N.E.2d 683, 688 (6th Dist. 2005). Of note, "[t]he existence of a duty is fundamental to establishing actionable negligence, without which there is no legal liability." *Uhl v. Thomas*, 12th Dist. No. CA 2008-06-131, 2009-Ohio-196, ¶ 10, quoting *Adelman v. Timman*, 117 Ohio App.3d 544, 549, 690 N.E.2d 1332 (8th Dist. 1997). The existence of a duty in a negligence action is a question of law for the court to determine. *Mussivand v. David*, 45 Ohio St.3d 314, 318, 544 N.E.2d 265, 270 (1989)(citing *Railroad Co. v. Harvey*, (77 Ohio St. 235, 240(1907))). There is no formula for ascertaining whether a duty exists. Duty is the court's "expression of the sum total of those considerations of policy which lead the law to say that the particular plaintiff is entitled to protection." *Id.*

(citation omitted). Any number of considerations may justify the imposition of duty in particular circumstances, including the guidance of history, our continually refined concepts of morals and justice, the convenience of the rule, and social judgment as to where the loss should fall. *Id.*

Ohio law does not impose a duty on physicians and/or medical clinics to regulate the pharmacies from which they lawfully purchase medications, nor does Ohio law impose a duty on physicians to visit and/or evaluate a licensed pharmacy's compounding facility prior to purchasing medications as Plaintiff has alleged. There is no authority supporting such a "due diligence duty." There is no support for such a imposition and no reported case has ever held or found such a duty. In this case, it was the duty of the Massachusetts Board of Pharmacy, not Dr. Batra and BKC Pain, to regulate and license NECC and to ensure NECC complied with Massachusetts' pharmacy laws. Dr. Batra/Dr. Katabay and BKC Pain were well within their legal right to purchase medication from a fully licensed pharmacy without ensuring the pharmacy's compliance with Massachusetts law. Additionally, Ohio law does not require physicians and/or clinics to purchase medications from an FDA regulated drug manufacturer as Plaintiffs suggest. Accordingly, Dr. Batra/Dr. Katabay and BKC Pain were fully permitted to purchase preservative-free MPA from a compounding pharmacy such as NECC and doing so did not breach any duty owed to Plaintiffs.

Contrary to the allegations, Dr. Batra/Dr. Katabay and BKC Pain were not required to follow the American Society of Health-System Pharmacy (ASHP) Guidelines on Outsourcing Sterile Compounding Services, nor do such guidelines establish any duty under Ohio law. ASHP is simply a professional organization for Health-System Pharmacies. It is not a governing body that has any authority over the actions of Ohio physicians and/or medical clinics, including Dr. Batra and BKC Pain. Thus, any "guidelines" promulgated by the organization do not establish

and/or constitute a due diligence obligation and duty on physicians/clinics purchasing compounded medications. Such guidelines are simply professional guidelines that have no bearing on duties imposed by Ohio law.

Simply put, Ohio law does not impose a duty on physicians to regulate pharmacies and/or engage in any type of due diligence prior to lawfully purchasing medications from a licensed pharmacy such as NECC. Ohio law has never recognized any such duties with respect to physicians and/or clinics. Moreover, it is for the Ohio General Assembly, not the courts, to determine whether any such duties should be imposed on physicians and/or clinics. See generally, *Crum v. Lambe*, 1987 WL 15496 (Ohio App. 4 Dist. 1987) (major shifts or creation of common law duties are matter of public policy better left for the legislature); see generally, *Bissen v. Fujii*, 446 A.2d 429, 431 (Haw. 1970) (“we should recognize that although courts at times arriving at decisions have taken into consideration social needs and policy it is the paramount rule of the legislature as a coordinate branch of court government to meet the needs and demands of changing times and legislate accordingly); Stephen Presser, *The Development and Application of Common Law*, 8 Tex. Rev. L. & Pol. 291, 296-97 (2004) (“[role of judge] you recognize that your job is to preserve the past, with its core system of values. You defer to the other institutions of republican government when it comes to policy making ...); *Badillo v. Am. Branch*, 16 P.3d 435, 441 (Nev. 2001) (lack of consensus as to medical monitoring militates toward rejecting judicial expansion of common law); *Coombes v. Florio*, 877 N.E. 567, 583 (Mass. 2007) (Marshall, C.J. dissenting) (advocating rejection of expanding physicians’ tort liability given how reasonable minds may differ on issue).

The only duty imposed on Dr. Batra/Dr. Katabay is the duty to exercise reasonable care in the care and treatment. Moreover, this duty of reasonable care is premised on consensus in the

medical community and there is no support whatsoever for an imposition of due diligence duty and would mark a drastic expansion of existing law and one better left to the legislature not the courts. Because the Complaints fail to allege a viable duty or breach of the standard of care or failed to act as a reasonably prudent physician would under the same or similar circumstances in his care and treatment Plaintiffs, Count III of Plaintiffs Complaint fails to state a claim upon which relief can be granted.

2. Plaintiffs Complaints fail to sufficiently allege causation.

Causation is an essential element of a negligence claim. See *Winkle v. Zettler Funeral Homes, Inc.*, 182 Ohio App.3d 195, 2009-Ohio-1724, 912 N.E.2d 151, ¶46 (“The essential elements for a negligence claim are duty, breach of duty, and damage or injury that is a proximate result of the breach.”). It consists of factual and proximate cause. Factual cause is the “but for” or “sine qua none” in which the negligent act is deemed the factual cause of an outcome if in the absence of the act, the outcome would not have been avoided. *Wesley v. Walraven*, 2013 WL 544053 (Ohio App. 4 Dist. 2013) citing *Anderson v. St. Francis- St. George Hosp., Inc.*, 77 Ohio St. 3d 82, 84-85, 671 N.E. 2d 225 (1996); Restatement (Third) of Torts, §26 cmt. b (2010). Proximate cause is generally established ““where an original act is wrongful or negligent and in a natural and continuous sequence produces a result which would not have taken place without the act.”” *Strother v. Hutchinson*, 67 Ohio St. 2d 282, 287, 423 N.E.2d 467 (1981), quoting *Clinger v. Duncan*, 166 Ohio St. 216, 217, 141 N.E.2d 156 (1957). “[W]here no facts are alleged justifying any reasonable inference that the acts or failure of the defendant constitute the proximate cause of the injury there is nothing for the jury [to decide], and, as a matter of law, judgment must be given for the defendant.” *Kemerer v. Antwerp Bd. of Edn.*, 105 Ohio App.3d

792, 796, 664 N.E.2d 1380 (3d Dist. 1995), quoting *Case v. Miami Chevrolet Co.*, 38 Ohio App. 41, 45–6, 175 N.E. 224 (1st Dist. 1930).

Indeed, “legal responsibility must be limited to those causes which are so closely connected to the result and of such significance that the law is justified in imposing liability.” *Wesley*, *supra* citing *Johnson v. Univ. Hosp. of Cleveland*, 44 Ohio St. 3d 49, 57, 540 N.E. 2d 1370 (1989). Moreover, “a court concludes, as a matter of law, whether consequences that are part of a natural and continuous sequence are, because of public policy grounds, too remote to impose liability for negligent acts or omissions.” *Queen City Terminal Inc. v. General Am. Transp. Corp.*, 1993 WL 538922 (Ohio App. 1 Dist. 1993) citing *Wright v. Cincinnati N.O. & T. P.D. Co.*, 107 Ohio App. 310, 314, 152 N.E. 2d 421, 423 (1958)

It is alleged that that Dr. Batra/Dr. Katabay and BKC Pain were negligent in failing to provide patient-specific prescriptions and/or in providing “fake” patient lists in order to purchase medication from NECC. Assuming *arguendo* such allegations are true – which they are not – such allegations are insufficient to plead causation, either factual or proximate. NECC’s failure to properly manufacture and apply proper sterility practices as to the preservative-free MPA is the source of the contamination, not Dr. Batra/Dr. Katabay’s alleged failure to provide patient-specific prescriptions. As such, the contamination would have occurred irrespective of whether patient-specific prescriptions were provided when purchasing the medication from NECC. Accordingly, the allegation that Dr. Batra and/or BKC Pain failed to provide patient-specific prescriptions is insufficient to establish causation as a matter of law.

3. Plaintiffs Complaints fail to sufficiently allege gross negligence.

Ohio law defines gross negligence as the “failure to exercise any or very slight care” or “a failure to exercise even that care which a careless person would use.” *Posen v. Sitecon*,

L.L.C., 8th Dist. No. 86239, 2006-Ohio-3167, quoting *Thompson Elect., Inc. v. Bank One, Akron, N.A.*, 37 Ohio St.3d 259, 265, 525 N.E.2d 761 (1988). In the absence of any duty, a plaintiff's gross-negligence claim must fail as a matter of law. *Winkle*, 182 Ohio App.3d at 210, citing *Elite Designer Homes, Inc. v. Landmark Partners*, 9th Dist. No. 22975, 2006-Ohio-4079, ¶ 57.

As more fully set forth above, the purported "duties" set forth in Plaintiffs Complaints are not duties imposed on Dr. Batra/ Dr. Katabay and/or BKC Pain under Ohio law. Much like Plaintiffs' negligence claim, the gross negligence claim must fail as a matter of law. Further, while the allegations in Plaintiffs' Complaint are extensive, she has not alleged sufficient facts against Dr. Batra/Dr. Katabay and BKC Pain to support a gross negligence claim. They are not sufficient to establish Dr. Batra/Dr. Katabay and BKC Pain "fail[ed] to exercise any or very slight care'" or "fail[ed] to exercise even that care which a careless person would use" as required to support a gross negligence claim. Accordingly, as the Complaints fail to sufficiently allege a gross negligence claim Count III of Plaintiffs' Complaint must be dismissed.

B. Under Ohio law, physicians cannot be held liable for violations of the Consumer Sales Practices Act.

In Count IV of their Complaints, Plaintiffs attempt to assert a claim against Dr. Batra/Dr. Katabay and BKC Pain for purported violations of the Ohio Consumer Sales Practices Act (hereinafter "OCSPA"), O.R.C. § 1345.01 *et seq.* See Short Form Complaints. However, under Ohio law, transactions between physicians and their patients do not fall within the bounds of the OCSPA; therefore, Count IV of Plaintiffs' Complaint fails to state a claim upon which relief can be granted.

The OCSPA prohibits a supplier from committing an unfair or deceptive act or practice in connection with a consumer transaction. See R.C. 1345.02(A); see also *U.S. Bank v. Amir*, 8th

Dist. NO. 97438, 2012-Ohio-2772, ¶42. Significantly, a “[c]onsumer transaction’ does not include ... transactions between attorneys, **physicians**, or dentists **and their clients or patients....**” (Emphasis added.) R.C. 1345.01(A). Because the OCSPA requires the unfair or deceptive act to occur in the context of a “consumer transaction”, a patient cannot maintain an action against a physician under the OCSPA. See *Chiropractic Clinic of Solon v. Kutsko*, 92 Ohio App.3d 608, 611, 636 N.E.2d 422 (8th Dist. 1994) (holding a chiropractor fell within the definition of ‘physician’ under R.C. 1345.01(A); therefore, the trial court did not err in dismissing a patient’s claim for alleged violations of the OCSPA); *Summa Health Sys. v. Viningre*, 140 Ohio App.3d 780, 795, 749 N.E.2d 344 (9th Dist. 2000) (recognizing the OCSPA does not apply to claims by patients against physicians).

It is undisputed that Dr. Batra and Dr. Katabay are physicians within the meaning of the OCSPA and any and all claims Plaintiffs may against either of them, and BKC Pain as their employer, arise in the context of the physician-patient relationship between Plaintiffs and Dr. Batra and/or Dr. Katabay. Plaintiffs cannot maintain an action against Dr. Batra/Dr. Katabay or BKC Pain for violations of the OCSPA under any circumstance. Therefore, Count IV of fails to state a claim upon which relief can be granted and must be dismissed.

C. Plaintiffs Consented to the Steroidal Injections at Issue; Therefore, There Is No Viable Claim for Battery.

Under Ohio law, a person commits battery when he unlawfully strikes or touches another. *Anderson v. St. Francis-St. George Hosp.*, 83 Ohio App.3d 221, 225, 614 N.E.2d 841 (1st Dist. 1992), citing *Green v. Drungold*, 101 N.E.2d 906, 908 (1950). In a medical setting, if a physician treats a patient without authorization or **consent**, the physician has committed a technical battery. (Emphasis added.) *Marcum v. Holzer Clinic, Inc.*, 4th Dist. No. 03CA25, 2004-Ohio-4124, ¶37, citing *Lacey v. Laird*, 166 Ohio St. 12, 139 N.E.2d 25 (1956); *Anderson*, 83

Ohio App.3d 221; *Estate of Leach v. Shapiro*, 13 Ohio App.3d 393, 469 N.E.2d 1047 (9th Dist. 1984).

However, a physician's acts are lawful if the patient has **expressly consented** to the medical treatment. *Anderson*, 83 Ohio App.3d 221. When a defendant offers proof that a plaintiff has consented to a medical treatment and the plaintiff fails to present evidence that the physician's treatment was performed without consent or that the treatment exceeded his or her consent, there is a failure of proof on an essential element of battery. See *Lipp v. Kwyer*, 6th Dist. No. L-02-1150, 2003-Ohio-3988 (trial court properly granted summary judgment on plaintiff's battery claim where plaintiff consented to procedure employed).

In this case, the procedure at issue is the performance of epidural steroidal injections. Thus, if the plaintiffs consented to the performance of the steroidal injection procedures, they are unable to establish the elements of a battery claim. In an attempt to establish their claim for battery, Plaintiffs allege they "did not consent to the injection of contaminated drugs into [her] bod[y]". See Master Complaint at ¶297. However, several paragraphs later, Plaintiffs allege "[m]any, if not all, of the Clinic Related Defendants prepared Consent for Treatment Forms... **which Plaintiffs read and relied upon when agreeing to accept treatment...**" *Id.* at ¶302. Thus, even when accepting all of Plaintiffs allegations as true, they were provided with a Consent to Treatment Form, which they read, prior to agreeing to undergo the steroidal injections at issue and agreeing to accept treatment, i.e. plaintiffs consented to the performance of the injections. Accordingly, Count VIII of Plaintiffs' Complaint fails to state a claim upon which relief can be granted and must be dismissed.

D. Plaintiffs' Complaint Does Not Properly Allege Violations of the Ohio Products Liability Act.

1. The Master Complaint does not set forth a claim for violations of Ohio Products Liability law.

In their Short Form Complaints, Plaintiffs purport to incorporate by reference from the Master Complaint, a claim against Dr. Batra/Dr. Katabay and BKC Pain for alleged violations of the Ohio Products Liability Act (hereinafter "OPLA"). See Short Form Complaints, at p. 4. However, the Master Complaint does not set forth a claim for violations of the OPLA. To the contrary, Count IX of the Master Complaint sets forth a claim against the Tennessee Clinic Related Defendants only for alleged violations of Tennessee Products Liability law. See Master Complaint at p. 76. Unlike several other counts in the Master Complaint where Plaintiffs set forth statutory claims against the Clinic Related Defendants by listing the various state statutes that formed the basis of such claims – for example, Count IV and Count XII – Count IX is limited to the Tennessee Clinic Related Defendants and sets forth allegations specific to Tennessee law.

Further, in their Short Form Complaint, Plaintiffs have not set forth any allegations specific to their Ohio Products Liability claim. Without the necessary allegations in either the Master Complaint or the Short Form Complaint, Plaintiffs have not sufficiently plead a claim for violations of the OPLA in this case.

2. As providers of professional services, Dr. Batra, Dr. Katabay and BKC Pain cannot be held liable for alleged violations of Ohio Products Liability law.

Assuming arguendo Count IX of the Master Complaint is somehow sufficient to set forth a cause of action under the OPLA, Plaintiffs Complaint fails to state a claim on which relief can be granted as Dr. Batra, Dr. Katabay and BKC Pain cannot be held liable for Plaintiffs alleged injuries under the OPLA. Accordingly, Count IX must be dismissed.

The OPLA imposes liability on manufacturers and suppliers for damages resulting from defective products. See O.R.C. § 2307.71 et seq. A “manufacturer” can be held liable when the product at issue was defective 1) in manufacture or construction, 2) in design, 3) due to inadequate warning or instruction, or 4) because it did not conform to a representation made by the manufacturer. See O.R.C. § 2307.73. Similarly, a “supplier” can be held liable when the supplier itself was negligent or when the product in question left the supplier, it did not conform to a representation made by the supplier. See O.R.C. § 2307.78(A). In addition, a supplier can be held indirectly liable under several circumstances set forth in O.R.C. § 2307.78(B), including when, as in this case, the claimant will be unable to enforce a judgment against the manufacturer of that product due to the insolvency of the manufacturer. See O.R.C. § 2307.78(B)(2).

Under the OPLA, a manufacturer is a “person engaged in a business to design, formulate, produce, create, make, construct, assemble, or rebuild a product or a component of a product.” O.R.C. § 2307.71(A)(9). Here, Dr. Batra, Dr. Katabay and/or BKC Pain do not meet the definition of a manufacture under the OPLA, nor has Plaintiffs set forth any allegations establishing that they do.

Neither Dr. Katabay, Dr. Batra or BKC Pain Specialist constitute a “supplier” under the OPLA. The OPLA defines a “supplier” as: 1) a person that, in the course of a business conducted for the purpose, sells, distributes, leases, prepares, blends, packages, labels, or otherwise participates in the placing of a product in the stream of commerce; or 2) a person that, in the course of a business conducted for the purpose, installs, repairs, or maintains any aspect of a product that allegedly causes harm. O.R.C. § 2307.71(A)(15)(a). The OPLA specifically excludes from the definition of “supplier” a “provider of professional services who, incidental to a professional transaction the essence of which is the furnishing of judgment, skill, or services,

sells or uses a product.” O.R.C. § 2307.71(A)(15)(b); *see also* Restatement (Third) of Torts, Product Liability section 20 cmt. d (1998) (“in a strong majority of jurisdictions, hospitals are held not to be sellers of products they supply in conjunction with the provision of medical care, regardless of circumstances”); 65 ALR 5th 357 (“generally attempts to apply product liability principles to what would be conventional medical malpractice actions have been unsuccessful”).

Here, in these cases, Dr. Batra, Dr. Katabay and BKC Pain do not constitute a “supplier” within the meaning of the OPLA as the preservative-free MPA at issue (the product) was used by Dr. Batra/Dr. Katabay while providing professional services – in the form of medical care and treatment – to plaintiffs. The use of the preservative-free MPA was merely incidental to the medical services provided by Dr. Batra/Dr. Katabay. Dr. Batra/Dr. Katabay and BKC Pain cannot be held liable as a supplier under the OPLA. As none of the allegations in the Complaint are sufficient to establish Dr. Batra, Dr./Dr. Katabay and/or BKC Pain meet the definition of a manufacturer or supplier under the OPLA, Count IX fails to state a claim upon which relief can be granted.

E. Plaintiffs Complaint Does Not Sufficiently Set Forth a Failure to Warn Claim under Ohio Law.

1. The Ohio Products Liability Act abrogates common law failure to warn claims based on an allegedly defective product.

Ohio Revised Code § 2703.71 defines a “[p]roduct liability claim” as a “claim or cause of action that is asserted in a civil action pursuant to sections 2307.71 to 2307.80 of the Revised Code and that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question, that allegedly arose from ... any warning or instruction, or lack of warning or instruction, associated with that product...” See O.R.C. § 2307.71(A)(13). Significantly, the

OPLA abrogated all common law product liability claims or causes of action. See O.R.C. § 270.371(B); see also *Wimbush v. Wyeth*, 619 F.3d 632, 639 (6th Cir. 2010) (recognizing the OPLA abrogated all common law product liability claims or causes of action).

The essence of Plaintiffs' failure to warn claim (Count VIII) is that Dr. Batra/Dr. Katabay and/or BKC Pain failed to warn that plaintiffs were being provided or administered an "unsafe, unreasonably dangerous drug compounded by NECC". Such a claim falls squarely within the definition of a "products liability claim" as it involves the "lack of warning... associated with a product" and, therefore, is abrogated by the OPLA. As more fully set forth above, Dr. Batra/Dr. Katabay and BKC Pain cannot be held liable under the OPLA; therefore, Count VIII fails to state a claim upon which relief can be granted.

2. Plaintiffs Complaint fails to establish the necessary elements of a common law failure to warn claim.

Assuming arguendo Plaintiffs failure to warn claim is not abrogated by the OPLA, Plaintiffs Complaint fails to establish the necessary elements of a common law failure to warn claim. To that end, to prove a claim of negligent failure to warn, a plaintiff must establish: (1) **the defendant had a duty to warn**; (2) the duty was breached; and (3) the plaintiff's injury proximately resulted from the breach of duty. (Emphasis added.) *In re Whirlpool Corp. Front-Loading Washer Products Liab. Litig.*, 722 F. 3d 838, 853 (6th Cir. 2013), citing *Hanlon v. Lane*, 98 Ohio App.3d 148, 648 N.E.2d 26, 28 (9th Dist. 1994). A plaintiff must show "that in the exercise of ordinary care, the [defendant] knew or should have known of the risk or hazard about which it failed to warn" and "that the [defendant] failed to take the precautions that a reasonable person would have taken in presenting the product to the public." *Id.*, citing *Doane v. Givaudan Flavors Corp.*, 184 Ohio App.3d 26, 919 N.E.2d 290, 296 (1st Dist. 2009).

The Complaint does not contain any allegations that the use of preservative-free MPA or a compounded drug, generally, presents a high-risk to patients or is unreasonably dangerous. Additionally, the Complaint does not contain any allegations that Dr. Batra/Dr. Katabay and/or BKC Pain knew or should have known that using preservative-free MPA or a compounded drug is unsafe or more dangerous than using a drug produced by an FDA-regulated manufacturer. Further, the Complaint does not allege Plaintiffs would have in fact refused to undergo the epidural steroidal injections at issue if she had been informed the drug being used was preservative-free MPA that had been obtained from a compounding pharmacy. Quite simply, the Complaint does not contain the necessary allegations to establish a common law failure to warn claim.

Moreover, contrary to Plaintiffs claims, Ohio law does not impose a duty on physicians to inform patients where drugs are produced or that a drug being used in the course and scope of their treatment was produced at a compounding pharmacy instead of an FDA-regulated pharmaceutical manufacturer. Thus, any failure on the part of Dr. Batra/Dr. Katabay and/or BKC Pain to provide such information cannot form the basis of a common law failure to warn claim. Accordingly, Count VII is insufficient as a matter of law and must be dismissed.

F. Plaintiffs Complaint Does Not Adequately Allege the Elements Necessary to Create an Agency Relationship under Ohio law.

Ohio law defines an agency relationship as a consensual, fiduciary relationship between two persons where the agent has the power to bind the principal by his or her actions, and the principal has the right to control the actions of the agent. *Evans v. The Ohio State Univ.*, 112 Ohio App.3d 724, 744 (10th Dist. 1996). To that end, an agency relationship exists “when one party **exercises the right of control over the actions of another**, and those actions are directed toward the attainment of an objective which the former seeks.” (Emphasis added.) *Mermer v.*

Medical Correspondence Services, 115 Ohio App.3d 717, 721 (6th Dist. 1996), citing *Hanson v. Kynast*, 24 Ohio St.3d. 171 (1986). “The important element in determining the existence of an agency relationship is the existence of control over the conduct and activities of the alleged agent.” *Adlaka v. Valley Elec. Consol., Inc.*, 11th Dist. No. 2007-T-0071, 2008-Ohio-1690, ¶¶27-28, citing *Haluka v. Baker*, 66 Ohio App. 308 (9th Dist. 1941). Of note, the party alleging the existence of an agency relationship bears the burden of proving that such a relationship exists. *Nee v. State Indus., Inc.*, 8th Dist. No. 99505, 2013-Ohio-4794, ¶63.

Significantly, the Complaint does not contain any allegations establishing Dr. Batra/Dr. Katabay or BKC Pain exercised the control over the actions of NECC that is necessary to establish an agency relationship between Dr. Batra/Dr. Katabay and/or BKC Pain and NECC. To that end, BKC Pain, and Dr. Batra/Dr. Katabay as its agents, and NECC are separate and distinct business entities with no legal relationship linking them together. Plaintiffs have not alleged, nor could she, that Dr. Batra/Dr. Katabay and/or BKC Pain exhibited any control, let alone the amount of control necessary to create an agency relationship, over the actions of NECC. Accordingly, the Complaint does not sufficiently allege the existence of an agency relationship between Dr. Batra/Dr. Katabay and/or BKC Pain and NECC.

In an apparent attempt to establish the element of control necessary to create an agency relationship, the Complaint states, in pertinent part: “[Dr. Batra/Dr. Katabay and BKC Pain] controlled the procurement of drugs from NECC...” However, the above-mentioned allegation does not allege the amount or type of control necessary to create an agency relationship. While creative, alleging Dr. Batra/Dr. Katabay and BKC Pain controlled the procurement of drugs from NECC is not remotely tantamount to alleging Dr. Batra/Dr. Katabay and/or BKC Pain controlled the actions of NECC. To the contrary, “controlled the procurement” simply means Dr. Batra/Dr.

Katabay and/or BKC Pain purchased medications from NECC. Thus, the only allegation relative to any amount of control between Dr. Batra and/or BKC Pain and NECC is insufficient to establish the control necessary to create an agency relationship under Ohio law.

Simply put, the purchase of medication by a doctor's office from a pharmacy does not create an agency relationship. If such acts created an agency relationship, nearly every retailer would be acting as an agent of every consumer that has ever made any purchase with the retailer. Because the purchase of medication from a pharmacy is an act of free choice and does not require or exhibit a scintilla of control by the doctor's office over the pharmacy, Plaintiffs cannot establish the level of control necessary to hold Dr. Batra/Dr. Katabay and BKC Pain liable for the actions of NECC. Accordingly, the allegations in the Complaint do not set forth the necessary elements of an agency relationship sufficient to hold Dr. Batra/Dr. Katabay and BKC Pain liable for the actions of NECC. Count X of the Complaint must be dismissed.

G. The Allegations in Plaintiffs Complaint Do Not Meet the Requirements of a Civil Conspiracy Claim under Ohio Law.

Ohio defines civil conspiracy as “a malicious combination of two or more persons to injure another in person or property, in a way not competent for one alone, resulting in actual damages.” *Fed. Ins. Co. v. Webne*, 513 F. Supp.2d 921, 926-27 (N.D. Ohio 2007), quoting *Kenty v. Transamerica Premium Ins. Co.*, 72 Ohio St.3d 415, 419, 650 N.E.2d 863 (1995) (internal citation omitted). To establish a claim of civil conspiracy, a plaintiff must allege: 1) a malicious combination; 2) of two or more persons; 3) injury to person or property; and 4) **existence of an unlawful act independent from the actual conspiracy**. (Emphasis added.) *Id.* Malice “is that state of mind under which a person does a wrongful act purposely, without a reasonable or lawful excuse, to the injury of another.” *Ohio Bureau of Workers’ Comp. v. MDL Active Duration Fund, Ltd.*, 476 F. Supp.2d 809, 825 (S.D. Ohio 2007), quoting *Pickle v. Swinehart*,

170 Ohio St. 441, 443, 166 N.E.2d 227 (1960) (internal citation omitted). An underlying unlawful act or tort is required before a party can prevail on a civil conspiracy claim. *Dickerson Internationale, Inc. v. Klockner*, 139 Ohio App.3d 371, 380, 743 N.E.2d 984 (2nd Dist. 2000).

The allegations set forth in the Complaint do not meet the requirements of a civil conspiracy claim. The Complaint does not allege a “malicious combination” between Dr. Batra/Dr. Katabay and/or BKC Pain and NECC. While it is alleged that defendants’ “acted in concert”, such an allegation is not a properly pled factual allegation necessary to survive a motion to dismiss. Also it does not rise to the level of a “malicious combination” as there is no allegation Dr. Batra/Dr. Katabay and/or BKC Pain acted with the purpose or intent of circumventing the Massachusetts Board of Pharmacy rules and regulations or that Dr. Batra/Dr. Katabay and BKC Pain purposely or intentionally provided “fake” patient lists – which they did not. Additionally, the Complaint does not set forth any allegations that Dr. Batra/Dr. Katabay and/or BKC Pain acted with the purpose or intent to injure. In the absence of such “factual” allegations, the Complaint does not adequately allege the first and second elements of a civil conspiracy claim.

Finally, the Complaint fails to allege an unlawful act on the part of Dr. Batra/Dr. Katabay and BKC Pain separate and apart from the alleged conspiracy. As Dr. Batra/Dr. Katabay and BKC Pain are not in Massachusetts, did not provide treatment to Plaintiffs in Massachusetts, are not pharmacists and/or licensed by the Massachusetts Board of Pharmacy, nor are they subject to the rules and regulations of the Massachusetts Board of Pharmacy. Accordingly, their alleged violation of such rules and regulations does not constitute an “unlawful act”. Further, failing to provide patient lists and/or providing a “fake” list of patient

names to NECC pursuant to its own request is not an “unlawful act independent from the actual conspiracy” for which Dr. Batra/Dr. Katabay and BKC Pain can be held liable.

The Complaint fails to adequately factually allege a claim for civil conspiracy under Ohio law. They have failed to allege both a malicious combination on the part of Dr. Batra/Dr. Katabay and/or BKC Pain or that either Defendant acted for the purpose of injuring Plaintiffs. Furthermore, neither Dr. Batra/Dr. Katabay nor BKC Pain had any duty to abide by the rules and regulations of the Massachusetts Board of Pharmacy or provide it with patient lists to purchase preservative-free MPA from NECC. Thus, in addition to failing to properly allege the first and second elements of a civil conspiracy claim, Plaintiffs have not alleged an underlying unlawful act by Dr. Batra/Dr. Katabay or BKC Pain. Count XI of the Complaint must be dismissed.

H. The Allegations Against Dr. Batra/Dr. Katabay and BKC Pain Specialists, LLC are Insufficient to Support a Punitive Damages Claim under Ohio Law.

In Count XIV of the Complaint, Plaintiffs have attempted to assert a punitive damages claim against Dr. Batra/Dr. Katabay and BKC Pain. See Master Complaint at p. 86; Short Form Complaint at 4. However, none of the allegations are sufficient to support a punitive damages claim. Indeed, a punitive damages claim is a derivative claim that cannot stand when the underlying tort claims are insufficient as a matter of law. Accordingly, Count XIV of the Complaint fails to state a claim upon which relief can be granted.

Under Ohio law, courts may award punitive damages in a tort action only upon a finding that the defendant committed a fraud or insult or that the defendant acted with “actual malice.” *Preston v. Murty*, 32 Ohio St.3d 334, 334-335, 512 N.E.2d 1174 (1987). The Ohio Supreme Court has defined “actual malice” as “(1) that state of mind under which a person’s conduct is characterized by hatred, ill will or a spirit of revenge, *or* (2) a conscious disregard for the rights

and safety of other persons that has a great probability of causing substantial harm.” (Emphasis sic.) *Id.* at syllabus.

Significantly, malice of the “conscious disregard” variety requires a higher culpability than acting “knowingly” under the Ohio criminal code and a higher culpability than acting with “recklessness” under the Restatement (2d) of Torts. *Spalding v. Coulson*, 8th Dist. Nos. 70524/70538, 1998 WL 564054, *16 (Sept. 3, 1998). In that regard, in *Spalding*, the court stated, in pertinent part:

In short, to warrant the imposition of additional punitive damages, above and beyond compensatory damages, the tort must be committed with a particularly depraved mental state. **In its basest form, it requires showing not only that the tortfeasor intended his act, but also deliberately intended to injure others. Its lesser forms include the tortfeasor’s perverse willingness to ignore consciously almost certain injury from his action.** The imminent harm disregarded must be substantial. **Recklessness, carelessness, or ignorance of the actor do not justify the imposition of punitive damages.** (Citations omitted.)

(Emphasis added.) *Id.* Thus, “a principle inherent in the award of punitive damages is that something more than mere negligence is always required.” *Preston*, 32 Ohio St.3d at 335, citing *Leichtamer v. American Motors Corp.*, 67 Ohio St.2d 456, 472, 424 N.E.2d 568 (1981). Further, otherwise sufficient evidence of compensatory damages will not automatically result in an assessment of punitive damages. *Motorists Mut. Ins. Co. v. Said*, 63 Ohio St.3d 690, 696, 509 N.E.2d 1228 (1992).

When proceeding on the “conscious disregard” definition of malice under *Preston*, a punitive damages claim requires proof of the defendant’s subjective knowledge of the danger posed to another by his conduct. *Estate of Schmidt v. Derenia*, 158 Ohio App.3d 738, 743-744, 822 N.E.2d 401 (10th Dist. 2004), citing *Malone v. Courtyard by Marriott L.P.*, 74 Ohio St.3d 440, 659 N.E.2d 1242 (1996), syllabus. “Since punitive damages are assessed for punishment and not compensation, a positive element of conscious wrongdoing is always required.” *Preston*,

32 Ohio St.3d at 335. The party must possess knowledge of the near certainty that substantial harm will be caused by the tortious behavior. *Estate of Schmidt*, 158 Ohio App.3d at 743-744. “Any less callous mental state is insufficient to incur that level of societal outrage necessary to justify an award of punitive damages.” *Motorists Mut. Ins. Co.*, 63 Ohio St.3d at 698, citing *Preston*, 32 Ohio St.3d at 336.

The Complaint does not contain any allegations sufficient to establish Dr. Batra/Dr. Katabay and BKC Pain acted with the actual malice necessary to support a claim for punitive damages in this case. To that end, Plaintiff has not set forth any allegations establishing that at the time of Plaintiffs respective injections, Dr. Batra/Dr. Katabay intended to inject her with medication that may be contaminated. Accordingly, the Complaint does not adequately set forth a claim for punitive damages under the first prong of *Preston*.

While Plaintiffs have set forth the bare legal conclusion that Dr. Batra or Dr. Katabay “were aware of, but consciously disregarded, a substantial and unjustifiable risk of such a nature that [his] disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under the circumstances”, they have not set forth sufficient factual allegations to support the assertion that either Dr. Batra or Dr. Katabay were aware, or should have been aware, of any substantial and unjustifiable risk posed by using preservative-free MPA obtained from NECC. Specifically, they have not set forth any allegations sufficient to establish Dr. Batra/Dr. Katabay had the subjective knowledge of the danger posed by purchasing preservative-free MPA from NECC that is required under the second-prong of *Preston*.

Plaintiffs have likewise not cited to any Ohio law, either common law or statutory, that establishes any duty on the part of Dr. Batra or Dr. Katabay to 1) purchase medications from a FDA-approved manufacturer, or 2) ensure NECC was in compliance with Massachusetts

pharmaceutical laws, or 3) inspect and/or visit NECC's facilities prior to purchasing preservative-free MPA from it. Even allegations of, "[r]ecklessness, carelessness, or ignorance of the actor do not justify the imposition of punitive damages" under Ohio law. *Spalding*, 1998 WL 564054 at *16.

Further, the Ohio Supreme Court has held that "no civil cause of action in this state may be maintained simply for punitive damages." *Intercity Auto Sales, Inc. v. Evans*, 8th Dist. No. 95778, 2011-Ohio-1378, ¶27, quoting *Niskanen v. Giant Eagle, Inc.*, 122 Ohio St.3d 486, 2009–Ohio–3626, 912 N.E.2d 595, ¶ 13; see also *Moskovitz v. Mt. Sinai Med. Ctr.*, 69 Ohio St.3d 638, 650, 1994–Ohio–324, 635 N.E.2d 331, which held that, since "punitive damages are awarded as a mere incident of the cause of action in which they are sought * * *, compensable harm stemming from a cognizable cause of action must be shown to exist before punitive damages can be considered." As more fully set forth above, Plaintiffs have not set forth a cognizable cause of action against Dr. Batra/Dr. Katabay and BKC Pain. Accordingly, the claim for punitive damages is insufficient under Ohio law. , Dr. Batra, Dr. Katabay and BKC Pain are entitled to dismissal of Count XIV of Plaintiff's Complaint.

V. CONCLUSION

For the foregoing reasons, Defendants, Adil Batra, M.D., Dr. Adil Katabay and BKC Pain Specialists, LLC, respectfully request the Complaints in the three actions (Montee v. BKC Pain Specialists LLC, et al No: 1:13-cv-12657-FDS; Cooper v. BKC Pain Specialists, LLC et al

No: 1:13-cv-12658-FDS; and Cooper v. BKC Pain Specialist LLC et al No. 1:13-cv-12659-FDS.) be dismissed, with prejudice, pursuant to Fed.R.Civ.P. 12(b)(6).

Respectfully Submitted
The Defendants
BKC PAIN SPECIALISTS, ADIL KATABAY,
M.D. and NIKESH BATRA, M.D.,
By their attorney,

/s/ Tory A. Weigand

I hereby certify that this document(s) filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on **February 7, 2014**

/s/ Tory A. Weigand

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